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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,355	02/14/2002	Hildegard M. Kramer	5190	8887

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EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,355	KRAMER ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *13,14 and 17-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application claims benefit to provisional application 60/268,559, filed February 14, 2001 (as set forth in declaration and application data sheet)

Claims 1-53 are pending.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on July 12, 2004, is acknowledged. The traversal is on the ground(s) that the Examiner has failed to specifically set forth one example for restricting a product from method of making, and instead has relied on a general statement of what was known in the art, citing MPEP 806.5(f). Further, it is argued that Examiner has failed to distinguish the products of Groups II and III, in particular since Group III is made by using the product of Group II. This is not found persuasive because MPEP 806.05(f) suggest but does not require specific examples to distinguish a product from a method of making ("Allegations of different processes or products need not be documented." MPEP 806.05(f)). It is noted further that a "product defined by the process by which it can be made is still a product claim (*In re Bridgeford*, 357 F.2d 679, 149 USPQ 55 (CCPA 1966)) and can be restricted from the process if the examiner can demonstrate that the product as claimed can be made by another materially different process" (MPEP 806.05(f)). However, it is noted that if applicant convincingly traverses the requirement, the burden shifts to the examiner to document a viable alternative process or product, or withdraw the requirement. In this case, Applicants traverse the restriction requirement noting that no alternative method for making the claimed product is

provided. Claim 14 encompasses fleece produced by the method of claim 10, where this method comprises shredding the fleece made by providing a crosslinking biodegradable macromer and crosslinking it to produce fleece (claim 1). The specification provides working examples that use crosslinked FOCALSEAL™ in the construction of fleece. While the methods recite making a desired shape and shredding presumably affects the size, the product claims simply encompass any shape and size of crosslinked FOCALSEAL™ . Ranger WR, *et al.* (Pneumostasis of experimental air leaks with a new photopolymerized synthetic tissue sealant. Am Surg. 1997 Sep;63(9):788-95) teach the use of FOCALSEAL™ that has been crosslinked to seal a wound. By the results present by Ranger et al. it appears that it was of a desired size capable of sealing the wound. The product claims broadly encompass any crosslinked biodegradable polymer, including natural materials such as celluloses (page 11 of the specification) or even UV-crosslinked polynucleotides for any variety of purposes (pages 19-22). A specific example was not provided because of the great scope and nature of the claimed invention encompassing even natural products as suggested by the instant application.

Applicants do not traverse the restriction of Group IV form the other groups, therefore, the restriction requirement of this group is maintained for the reasons of record.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-54 are pending. Claims 13, 14, 17-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 17, 2004. Claims 1-12, 15, 16, drawn to a method of

making a biocompatible fleece comprising providing solution of a macromer that is hydrophilic, biodegradable and a cross-linking moiety; freezing the solution into the desired shape and cross-linking into a fleece/matrix, is currently under examination.

As discussed above, it is note that the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP 821.04. In this case, Applicants have elected for examination the process not the product.

However, in the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so

may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The cited reference No 39 "The Fibrin Network..." , Baxter Hyland Immuno, pp.1-38 has been put in the file but not considered because a full citation is not provided, specifically setting forth the source or the publication date of the cited reference.

Specification

The disclosure is objected to because of the following informalities: the use of the trademark FOCALSEAL-S (page 31, line 13) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks..

Appropriate correction is required throughout the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4, 9, 12 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claim 3 is unclear because it requires vacuum-drying "the solution", however a solution would not exist after the cross-linking step.

Claim 4 is vague and unclear in the recitation of biologically active agent because the metes and bounds of the term is relative to how any given agent is used or viewed by the artisan. For example, a sample containing unpolymerized acrylamide may be viewed as being a biological agent because it can be a neurotoxin. The claim is indefinite because the term active agent is not clearly defined in the claim nor the specification.

Claims 9, 10 and 15 are incomplete because how a sample is "shredded" is not clearly set forth, in particular for fleece particles that are small. Further, if a polymer was formed it is unclear how one would distinguish what are "fleece particulates".

Claim 12 is vague in the recitation of "supporting material" because what would be considered a supporting material and how it "is incorporated" would be subject to different interpretation of the term "supporting".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-12, 15, 16 are rejected under 35 U.S.C. 102(b) as being anticipate by DeLuca *et al.* (US Patent 4,741,872 issue date May 3, 1988).

The claims encompass a process for making fleece comprising the steps of providing a crosslinking polymer in a solution, freezing the solution, crosslinking the polymer, and drying the solution. Dependent claims set forth adding specific agents to the fleece produced and specific steps of polymerizing and post-processing of the fleece. The term fleece is generally described with functionally attributes in the specification (page 6, lines 3-9) and specific cross-linking groups and chemistries are set forth starting at page 8 and specific examples are set forth in Example 1 (as taught for example in US Patent 6,083,524 and 5,410,016).

DeLuca *et al.* teach a process for making biodegradable microspheres by polymerizing macromers including those set forth in the instant specification. Further, DeLuca *et al.* teaches the addition of agents such as drugs to the polymer in addition to washing and freeze-drying steps (see for example Figure 1).

Claims 1-12, 15, 16 are rejected under 35 U.S.C. 102(b) as being anticipate by Yannas *et al.* (US Patent 4,955,893).

Yannas *et al.* teach a method of promoting nerve regeneration by providing a biodegradable polymer. The polymer is made by a process of axial freezing to produce a structure with orientated pores. Further, Yannas *et al.* teaches that the biological active agent glycosaminoglycan can be added to the polymer that is generated. Finally, Yannas *et al.* teach that the polymer can be freeze-dried for storage.

Claims 1-12, 15, 16 are rejected under 35 U.S.C. 102(b) as being anticipate by Yannas *et al.* (US Patent 4,741,872).

Similar to the teaching of DeLuca *et al.*, Yannas *et al.* teach a process for making biodegradable microspheres by polymerizing macromers encompassed by the instant claims. Yannas *et al.* teach the addition of agents such as GAG to the polymer in addition to washing and freeze-drying steps for storage.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach